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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/821,001 | 04/07/2004 | Peter Palese | NS104D1C1 | 9293 |

36577 7590 01/02/2008

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| EXAMINER | |
|---|---|
| GUZO, DAVID | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1636 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 01/02/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/821,001 | PALESE ET AL. | |
| | Examiner | Art Unit | |
| | David Guzo | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on 10/12/07

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 81,82,85-89 and 92-105 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 81,82,85-89 and 92-105 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## Detailed Action

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/12/07 has been entered.

## Obviousness Type Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 81-82, 85-89, 92-105 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,820,871 (hereafter the '871 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite compositions comprising influenza virus particles with recombinant (mutated) gene sequences encoding HA, PB1, PB2, PA and matrix proteins. Both sets of claims recite vaccine compositions comprising the recombinant influenza viruses. With regard to instant claims reading on attenuated (or killed) influenza virus particles, this would be an obvious embodiment because use of attenuated or killed influenza virus particles is standard in vaccine preparations. With regard to mutating the HA protein at the HA protein cleavage site, this embodiment would have been obvious since the '871 specification specifically teaches mutation at the HA protein cleavage site so as to attenuate the virus. With regard to the instantly claimed vaccine compositions which are recited as suitable for intranasal administration, it is noted that administration of viruses infecting the respiratory tract are routinely administered by an intranasal route since the immune response elicited by said administration mimics the natural immune response to natural influenza virus.

**35 USC 103(a) Rejections**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 81-82, 85-89 and 92-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enami et al. in view of McCauley et al.

Applicants claim compositions (can be vaccine compositions) comprising influenza virus particles wherein said particles comprise a recombinant vRNA segment and wherein said segment can encode a hemagglutinin, RNA-directed RNA polymerase, nucleoprotein, or matrix protein. The virus particles can also be attenuated or killed and the vaccine compositions can be formulated for intranasal administration.

Enami et al. (cited by applicants, PNAS, May 15, 1990, Vol. 87, pp. 3802-3805, see whole article, particularly the Abstract, 2nd paragraph on p. 3802, p. 3803, last two paragraphs on p. 3805) teaches generation of infectious influenza viruses wherein the particles comprise a recombinant RNA segment, wherein said segment encodes a neuraminidase (NA) protein. Enami et al. teaches that mutations can be recombinantly

introduced into any influenza gene or into nontranslated regions of the influenza genome so as to define the functions of each viral protein or better understand the regulatory signals present in the virus. Enami et al. also recite that recombinant influenza vaccines can be generated by introduction of sequences encoding foreign epitopes into the influenza viral genome. Enami et al. does not reduce to practice the generation of recombinant influenza viruses, other than those with mutations in the segment encoding the NA protein, and does not reduce to practice influenza vaccines.

McCauley et al. (Biochem. J., 1983, Vol. 211, pp. 281-294, see whole article, particularly Table 1) teaches the structure and function of the influenza virus genome.

The ordinary skilled artisan would have been motivated to use the teachings of Enami et al. on generation of recombinant influenza viruses with mutations in the NA gene to generate recombinant influenza viruses with mutations in other influenza genes (influenza genomic structure reviewed by McCauley et al.) so as to study the biological properties of the viral genes or nontranslated regions and/or to generate vaccines. Mutation sites such as the cleavage site of the HA protein would have been obvious since the HA cleavage site was well known and was known to be essential in HA activity (McCauley et al., page 282, left column). With regard to the generation of influenza vaccines, the virus, as a matter of course, would need to be attenuated or killed so as not to generate an active infection in the person inoculated. Given that Enami et al. provides the teachings necessary to generate recombinant influenza viruses and recites that any gene of the influenza virus genome can be mutated and recites that recombinant influenza viruses can be generated as vaccines and given that the genome

of influenza viruses was well known (McCauley et al.) and influenza vaccines were widely used, it must be considered that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention. Given the teachings of the prior art and the high level of skill of the ordinary skilled artisan at the time the invention was made, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D., can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


David Guzo
December 18, 2007